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08/566038

APPLICATION NUMBER 08/566038	FILING DATE 05/05	ROUSSTOTT	FIRST NAMED APPLICANT	V	ATTY. DOCKET NO.
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18M1/0805

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EXAMINER

GAMBEL, P

ART UNIT

PAPER NUMBER

1806

DATE MAILED: 08/05/97

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on 4/6/97
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 30 MYC month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 48-101 is/are pending in the application.
- Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☒ Claim(s) 48-101 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

### DETAILED ACTION

1. Applicant's amendment, filed 4/21/97 (Paper No. 6), is acknowledged.  
Claims 1-47 have been canceled.  
Claims 48-101 have been added.

2. It is noted that applicant has consolidated the claims under the general preamble of "methods of modulating T cell unresponsiveness". However the claims are still drawn to distinct and independent inventions in that the claims are drawn to either stimulating T cell proliferation or to inhibit (induce unresponsiveness) T cell responsiveness. Stimulating and inhibiting T cell responsiveness differ in the method objectives, method steps and parameters and in the reagents used. Therefore the following Restriction is made with respect to the instant claims. It is noted that certain claims are common between the Groups, however the Groups are independent and distinct inventions for the reasons of record set forth in the previous Office Action and reiterated herein.

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. Claims 48-70, 98-101, drawn to methods for stimulating proliferation by a T cell which expresses a cytokine receptor gamma chain using an agent that binds to the cytokine receptor gamma chain, classified, for example, in Class 424, subclass 144.1 and Class 514, subclass 8.

- II. Claims 48, 71-97 and 98, drawn to methods for inducing unresponsiveness to an antigen in a T cells which expresses a cytokine receptor gamma chain, classified, for example, in Class 424, subclass 144.1 and 145.1.

4. The inventions are distinct, each from the other because of the following reasons:

The methods of Groups I-II differ in the method objectives, method steps and parameters and in the reagents used. Group I contains claims drawn to methods for stimulating proliferation by a T cell which expresses a cytokine receptor gamma chain using an agent that binds to the cytokine receptor gamma chain. Group II contains drawn to methods for inducing unresponsiveness to an antigen in a T cells which expresses a cytokine receptor gamma chain. These methods are clearly distinct as they are directed to opposing endpoints.

5. This application contains claims directed to the following patentably distinct species of the claimed invention I wherein the agent is:

- i) an anti-gamma chain antibody
  - ii) IL-4 or
  - iii) IL-7.

These species are distinct because their structures and modes of action are different which, in turn, address different conditions and endpoints.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 48 and 49 are generic.

6. This application contains claims directed to the following patentably distinct species of the claimed invention II wherein the agent is:

- i) an anti-gamma chain antibody
- ii) anti-IL-2 antibody,
- iii) anti-IL-4 antibody or
- iv) anti-IL-7 antibody.

These species are distinct because their structures and modes of action are different which, in turn, address different conditions and endpoints.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 48 and 71 are generic.

7. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

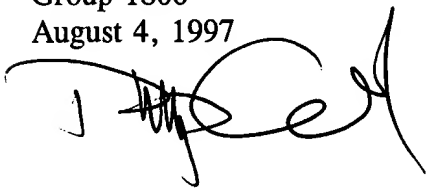
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee can be reached on (703) 308-2731. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1800 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [lila.feisee@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Phillip Gambel, PhD.  
Patent Examiner  
Group 1800  
August 4, 1997

A handwritten signature in black ink, appearing to be "P. Gambel", written over the typed name and date.